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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Douglas A. Amorese

Serial No.: 09/870,938

Examiner: Betty J. Forman

Filing Date: May 30, 2001

Group Art Unit: 1634

Title: COMPOSITE ARRAYS

COMMISSIONER FOR PATENTS
P.O. Box 1450
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TRANSMITTAL OF REPLY BRIEF

Sir:

Transmitted herewith is the Reply Brief with respect to the Examiner's Answer mailed on May 27, 2005. This Reply Brief is being filed pursuant to 37 CFR 1.193(b) within two months of the date of the Examiner's Answer.

(Note: Extensions of time are not allowed under 37 CFR 1.136(a).)

(Note: Failure to file a Reply Brief will result in dismissal of the Appeal as to the claims made subject to an expressly stated new grounds of rejection.)

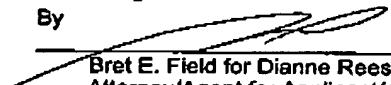
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Respectfully submitted,

Douglas A. Amorese

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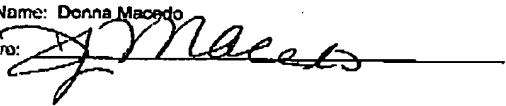
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REPLY BRIEF	Attorney Docket	10010791-1
Address to: Box DAC Assistant Commissioner for Patents Alexandria, VA 22313-1450	First Named Inventor	Douglas A. Amorese
	Application Number	09/870,939
	Filing Date	May 30, 2001
	Group Art Unit	1634
	Examiner Name	Betty J. Forman
	Title	COMPOSITE ARRAYS

Sir:

This Reply Brief is in response to the Examiner's Answer mailed by the Office on May 27, 2005.

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REPLY BRIEF

In this Reply Brief, the Appellants address several issues raised in the Examiner's Answer. The Appellants note that all arguments presented in the prior Appeal Brief still apply with equal force, but are not reiterated here solely in the interest of brevity and for the convenience of the Board.

In this Reply Brief, the Appellants address the following:

- a) the Examiner's assertion that the claims stand or fall together;
- b) the new grounds of rejection; and
- c) specific assertions made by the Examiner in responding to Appellants'

arguments.

Each of the above is set forth in turn and under separate headers, below.

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THE CLAIMS SHOULD NOT STAND OR FALL TOGETHER

On page 3 of the Examiner's Answer, the Examiner states that the rejection of claims 1-3, 5-20 and 38-41 stand or fall together because Appellants brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. The Examiner cites 37 C.R.F. 1.92(c)(7).

To the Appellants knowledge, 37 C.R.F. 1.92(c)(7) has been changed according to the amended rules set forth § 41.37 of the Federal Register Vol. 69, No. 155, published on August 12, 2004 and effective on September 13, 2004. The Appellants note that the amended rules do not require a statement indicating the "Grouping of Claims" in an Appeal Brief.

Instead, according to the amended rules, each group of claims may be independently argued under separate headers. In the Appeal Brief, claims 14 and 41 were independently argued under a separate header. As such, the Appellants submit that claims 1-3, 5-20 and 38-41 should not stand or fall together with claims 14 and 41.

NEW GROUNDS OF REJECTION

Claims 1-3, 5-14 and 38-41 are newly rejected under 35 U.S.C. § 112, first paragraph, as containing new matter.

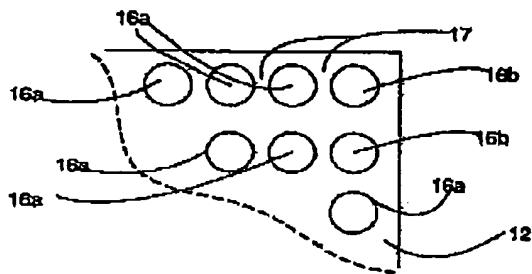
In the response filed on June 3, 2004, the Appellants attempted to amend the claims to clarify that the features in the first and second sets of features are spatially distinct. Towards this end, the Appellants amended the claims to recite a second set of features that is "independent of said first set of features".

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The Appellants submit that one of skill in the art would reasonably interpret independent features that are on the surface of an array as being spatially distinct from each other.

The Appellants submit that support for the amendment in question may be found throughout the instant specification, particularly on page 4, lines 13-19, as well as page 7, lines 19-27 and Figs. 2 and 5. For example, Fig. 2 of the instant application, illustrated below for the Boards' convenience, clearly illustrates features (e.g., features 16a and 16b, referred to in the specification as first and second sets of features, respectively) that are spatially distinct and independent from one another.

FIG. 2



In view of the foregoing discussion, the Appellants submit that there is clear support for the amendments made in the response of June 3, 2004.

Reversal of this rejection is respectfully requested.

SPECIFIC ASSERTIONS MADE BY THE EXAMINER IN RESPONDING TO APPELLANTS' ARGUMENTS

Claims 1-3, 5-10, 14, 38 and 41 stand rejected under 35 U.S.C. § 103(a) as being obvious over Bao (USPN 6,251,601) in view of Bobrow (USPN 6,399,299). The

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Examiner argues that Bao discloses a polynucleotide array containing different types of features that, in combination with Bobrow's polynucleotide array, renders the appealed claims obvious.

In the Appeal Brief, the Appellants argued that this rejection is deficient because:

a) a polynucleotide array containing both cDNA elements and synthetic oligonucleotide elements of the recited size limitations is not suggested by either of the cited references; and

b) the proposed modification to Bao's polynucleotide array would render the Bao's polynucleotide array unsatisfactory for its intended purpose.

In the Examiner's Answer, the Examiner responded by arguing that:

i) cDNAs and genomic fragments are indistinguishable and, as such, Bao's arrays (which contain oligonucleotides and genomic fragments) are not any different from the arrays being claimed (which contain oligonucleotides and cDNAs of defined lengths); and

ii) the intended use of a product has no relevance to the patentability of a claim directed to the product.

Each of the above arguments will be addressed under separate header below.

I. cDNAs and genomic fragments

The general thrust of the Examiner's response to the Appellants arguments (as set forth in the Examiner's Answer on page 5 onwards) is that cDNAs and genomic

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sequences are indistinguishable. As such, according to the Examiner, the claimed arrays (i.e., arrays that contain oligonucleotide features and *cDNA* features of defined lengths) are indistinguishable from those of Bao (who's array contain oligonucleotide features and *genomic fragment* features). In the Examiner's own words: "Genomic sequences, intron sequences, exon sequences and cDNA sequences all have the same components i.e. nucleotides (A, T, C, G) aligned in various combinations and lengths. While all types of nucleic acid sequences (genomic, intron, exon, cDNA) vary in length and arrangement of nucleotides, the content is the same i.e. nucleotides. Because genomic, intron, exon and cDNA sequences are not distinguishable by their length or content, it is unclear how, absent some unclaimed defining step, the genomic sequences of Bao et al are distinguishable over cDNAs as asserted."¹

In other words, the Examiner argues that the issue in this case is a matter of "distinguishing of cDNA sequences over genomic sequences"². Without such a distinction, it is unclear to the Examiner how the claimed arrays are distinguishable over those of Bao³.

In response, the Appellants submit that any molecular biologist would recognize that cDNAs and genomic fragments are different for quite a variety of reasons.

As is well known to one of skill in the molecular biology arts, cDNA is DNA that is produced by copying (e.g., by "reverse transcribing") an mRNA template. As such, cDNA molecules each generally contain a single open reading frame that encodes a

¹ See the paragraph staring at the bottom of page 5 of the Examiner's Answer.

² See Examiner's Answer page 6, lines 14-15.

³ See Examiner's Answer page 7 lines 1-2

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protein. cDNAs are generally relatively small in length (typically in the range of 500-5000 bp) and have a non-complex, defined nucleotide sequence. cDNAs do not contain intron sequences or any untranscribed sequences such as promoter sequences. At a molecular level, cDNA molecules generally contain a contiguous nucleotide sequence that can be directly translated to produce a protein.

A feature containing a cDNA can be used to reliably and specifically detect the mRNA transcription products of a single gene in a sample. Accordingly, one of skill in the art would readily employ an array of cDNAs to assess gene expression.

In contrast and as would be recognized by one of skill in the molecular biology arts, the genomic fragments employed in Bao's array are relatively long in length (i.e., 20,000 bp to 250,00 bp, as set forth on page 8, lines 57-58, of Bao's disclosure), and contain all types of non-coding sequences, including untranscribed regions, repetitive sequences, promoters, introns and intergenic regions. Because of the presence of introns in the vast majority of genes, genomic fragments generally do not contain a contiguous sequence of nucleotides that can be directly translated into a protein. Further, intron sequences, repetitive sequences, promoters, and intergenic sequences have distinct sequence characteristics. For example, intron sequences are characterized as having a higher AT content than coding sequences. Further, intron sequences contain splice site recognition sequences that cDNA sequences simply do not contain. Promoter regions, like introns, are also AT-rich as compared to coding sequences. Further, promoter regions contain regulatory sequences such as canonical TATAA boxes that cDNAs do not contain. Finally, cDNAs do not contain repetitive sequences such as Alu, LINE,

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SINE, micro-satellite or transposable element sequences. Such sequences are highly prevalent in the genomes of most higher eukaryotes.

Because genes vary enormously in length (i.e., from less than 1 kbp up to approximately 2.5 Mbp), in most cases a feature containing a genomic fragment cannot be used to reliably and specifically detect an mRNA transcription product of a single gene in a sample. One of skill in the art would not employ an array of genomic fragments such as that disclosed by Bao to assess gene expression.

In view of the above discussion, the Applicants submit that cDNAs and the genomic fragments employed by Bao are different, and readily distinguishable by one of skill in the art. Accordingly, one of skill in the art would recognize that the array of Bao (containing oligonucleotide and *genomic fragment* features) is not the same as the array recited in the appealed claims (containing oligonucleotide and *cDNA* features).

Appellants respectfully submit that the logic used by the Examiner to establish this rejection could be used to argue soot and diamonds are indistinguishable because they both are made up of carbon atoms. Like genomic fragments and cDNA, soot and diamonds may be made of the same building blocks (in this case carbon atoms rather than nucleotides). However, soot and diamonds are clearly different.

The secondary reference cited to establish this rejection is Bobrow. As argued in the Appeal Brief, Bobrow, like Bao, fails to specifically describe an array containing oligonucleotide elements and cDNA elements that are independent of each other, and

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nowhere teaches or suggests providing nucleic acid probes at independent features which differ in size as recited in the appealed claims.

Accordingly, Bao and Bobrow, taken independently or in any combination, fail to teach an element of the claims: an array containing independent oligonucleotide elements and cDNA elements with the recited size limitations stated in the claims.

In view of the foregoing discussion, the Appellants submit that the appealed claims cannot be rendered obvious by the combination of Bobrow and Bao because an element of the claims is not taught. In view of this, the Appellants submit to the Board that this rejection should be reversed.

ii. The intended use of Bao's array

In the Appeal Brief, the Appellants further questioned why one of skill in the art would be motivated to produce the array as recited in the appealed claims based on the disclosure of Bao, even considering Bobrow. The Appellants argued that one of skill in the art would not be motivated to modify Bao's array to meet the required limitations of the rejected claims because such a modification would render Bao's array unsatisfactory for its intended use. In other words, if Bao's array was modified to be an array meeting the requirements of the rejected claims, e.g., to become an array of cDNAs and oligonucleotides, such an array would be unsatisfactory for Bao's intended use, i.e., unsatisfactory for simultaneously detecting gene expression and genomic abnormalities (see Bao's title and col. 3, lines 1-3 of Bao's disclosure). Accordingly, one of skill in the art would not be motivated to make the necessary changes to Bao's array and, as such, Bao cannot render the appealed claims obvious.

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The Examiner dismissed this argument by simply stating: "arguments regarding an intended use are not relevant to the instant product claims"⁴ (underlining in the original).

In response, the Appellants acknowledge that the Examiner's statement may be applied with full force in a case in which a prior art reference *anticipates* a claimed invention. However, the Board is reminded that the rejections being argued are based on *obviousness*. This is not a case in which a prior art reference *anticipates* a claimed invention.

As pointed out in the Appeal Brief and as repeated for the Board's convenience below, MPEP § 2143.01 explicitly states that the intended use of a prior art product is of vital relevance in establishing a *prima facie* case of obviousness:

"If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)"

In other words, the MPEP states that if a rejection proposes a modification to a prior art product that would render the product unsuitable for its intended use, then there can be no motivation to make the proposed modification. Accordingly, if a rejection proposes such a modification, the rejection should be withdrawn.

Further, as noted above, the recitation of the term "cDNA" in the claims is not merely a reflection of an intended use of the subject matter being claimed. The term "cDNA" in the claims is an important requirement for a nucleic acid that does not contain intron, promoter and intergenic sequences. As noted above, one of skill in the art

⁴ See Examiner's Answer page 7, lines 3-10.

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would not employ the genomic fragments of Bao (which fragments contain intron promoter and intergenic sequences) to assess gene expression.

In view of the above, the Appellants submit that the Examiner's dismissal of the Appellants' prior arguments lack force. As such, the Appellants' prior arguments regarding the intended use of Bao's arrays still apply with equal force.

Reversal of the current rejections in view of the Appellants prior arguments is respectively requested.

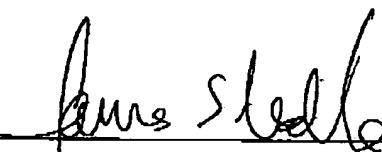
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The Appellants respectfully request that the rejection of claims 1-3, 5-20 and 38-41 under 35 U.S.C. §112, second paragraph and §103 be reversed, and that the application be remanded to the Examiner with instructions to issue a Notice of Allowance.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: July 15, 2005

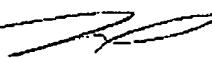
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